JUN - 1 2000

K001005

Wako

Wako Chemicals USA, Inc.
1600 Bellwood Road, Richmond, VA 23237 U.S.A.

510(k) Summary of Safety and Effectiveness

The Wako HDL/LDL Calibrator is designed to be used with Wako's Direct HDL and Direct LDL assays.

The safety and effectiveness of the Wako HDL/LDL Calibrator is demonstrated by its substantial equivalency to the Wako individual HDl & LDL Calibrators. Both calibration material are used to calibrate instruments to measure HDL-C and LDL-C in serum. In comparison studies against the predicate lipase standard, a correlation coefficient of 1.000 and a regression equation of y =0.99x -.02 was obtained.

March 27, 2000
Wako Diagnostics
Wako Chemicals USA, Inc.
1600 Bellwood Road
Richmond, VA 23237

Telephone (804) 271-7677 Facsimile (804) 271-7791

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 1 2000

Ms. Tonya Mallory
Senior Manager
Wako Diagnostics USA, Inc.
1600 Bellwood Road
Richmond, Virginia 23237

Re: K001005
Trade Name: Wako HDL-C/LDL-C Calibrator
Regulatory Class: II
Product Code: JIS
Dated: March 27, 2000
Received: March 29, 2000

Dear Ms. Mallory:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K001005

Device Name: Wako HDL-C/LDL-C Calibrator

Indications For Use:

Intended to be used to establish points of reference that are used to determine the HDL-C & LDL-C values with the Wako Direct HDL-C and Wako LDL-C test systems.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001005

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)